K010747

MAY 1 6 2001

510(k) SUMMARY

Western Medica
OPC Oxygen Conserving Regulator

1. Submitters Name, Address, Telephone/Fax Numbers, and Contact Person:

Submitter
Byron Crampton
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2. Date Prepared: March 12, 2001

3. Name of Device:

Trade Name: OPC Oxygen Conserving Regulator

Common Name: Oxygen Conserver

Classification Name: Ventilator, Non-continuous (Respirator)
(BZD73) 21CFR 868.5905

4. Predicate Devices:

1. Victor Equipment Company – O2N Demand-II (K992659)
2. Victor Equipment Company – OCPR (K963247)

5. Intended Use:

The OPC is intended to be used in home, respiratory, pulmonary, and skilled care facilities. It is an accessory to an oxygen supply system and is designed to conserve the oxygen being used by the patient, thus extending usable cylinder life. USP Oxygen is delivered to the patient (via cannula) by sensing the patient's breathing cycle or vacuum created for every breath. The unit is designed to deliver the prescribed flow rate (0-6 LPM) to the patient only during the inlet portion of the breathing cycle. The unit may also be set to provide continuous flow to the patient, independent of the breathing cycle, during high demand usage.

6. Technological Characteristics and Substantial Equivalence

a. Device Description:

The OPC conserving regulator is a pneumatic, aluminum preset regulator with an incorporated conserving device that senses the patients inhalation cycle and supplies the prescribed liter/minute flow of oxygen. It features aluminum construction with a brass high-pressure chamber, and attaches to standard oxygen CGA 870 yoke connection cylinders. A dual lumen cannula is attached to dual outlet ports: one port senses patient inhalation, while the other delivers oxygen. A cylinder contents gauge is mounted on the regulator and displays cylinder pressure, and is protected by a rubber shock ring. Available flow rates are: ½, 1, 2, 3, 4, and 5 liters per minute. The unit can operate in both conserving and continuous flow, by sliding a button located on the conserving portion of the regulator.

b. Substantial Equivalence:

The Western Medica OPC conserving regulator is substantially equivalent to other pneumatic conservers on the market, specifically the Victor O2N Demand-II model OCPR-II oxygen conserver (K992659) and Victor OCPR (K963247).

7. Performance Data

Extensive R&D testing has been performed on the OPC conserving regulator for functionality in the field. These tests include:

- Temperature
- Drop Testing/Packaging
- Flow Regulation
- Cycle
- Conservation
- Flow Response
- Pressure Testing

The testing performed confirms that the design intent and customer expectations were met and that the device complies with all FDA Good Manufacturing Practice (GMP) guidelines. The device meets all anticipated performance criteria and functions as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 16 2001

Mr. Byron Crampton
Western Enterprises
875 Bassett Road
Westlake, OH 44145-1142

Re: K010747
OPC Oxygen Conserving Regulator
Regulation Number: 868.5905
Regulatory Class: II (two)
Product Code: 73 BZD
Dated: March 12, 2001
Received: March 13, 2001

Dear Mr. Crampton:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010747

Device Name: **OPC Oxygen Conserving Regulator**

Indications For Use:

The OPC Conserving Regulator is used to deliver a prescribed flow of gas to the patient while conserving gas, by sensing the patient inhalation cycle and supplying gas only during that phase of breathing.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Only

(Optional Format 3-10-98)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010747